



Sunoptic International Ltd.
79 College Road,
Harrow, Middlesex
HA1 1BD, UK

Authorized representative:
Sunoptic Europe BV
Neerveld 11
2550 Kontich, BE

EC Declaration of conformity

Dear Sirs,

We, Sunoptic International Ltd., declare under our sole responsibility that products to which this declaration relates are in conformity with the following standards:

Name of Manufacturer (SRN): **SUNOPTIC INTERNATIONAL Ltd. (GB-MF-000009257)**

Authorized representative (SRN): **Sunoptic Europe BVBA (BE-AR-000003314)**

Product name: **Optical frames TR90 mix fullrim (models see annex)**

Description of products: **Optical frames designed to maintain the correct distance between the lenses and alignment relative to each eye**

Product identification by : **Name of product on polybag**

Brand Name: **Sunoptic / Montana**

Risk class: **Class I – non sterile, no measuring function - according to Rule 1, Chapter III, Annex VIII of the EU Regulation 2017/745**

Conformity assessment procedure: **Pursuant to article 52(7) for medical devices**

Nomenclature : **Code (UMDNS) 11-667, GMDN Code 32816**

Basic UDI-DI : **50558608fra-TR90-mix-frLH**

All products are marked with CE logo. The CE marking on the products and/or their packaging signifies that these have been produced with reference to the technical specifications of the European authorities.

Optical Frames of our production follow the specifications and requirements of the European Regulation on medical devices:

(EU) 2017/745. Conform EN ISO 12870

Regulation (EC) No 1907/2006

Sunoptic International Ltd.
Belgium, 01.01.2022

Bob Kenter
Director





Sunoptic International Ltd.
79 College Road,
~~Harrow, Middlesex~~
HA1 1BD, UK

Authorized representative:
Sunoptic Europe BV
Neerveld 11
2550 Kontich, BE

EG-Konformitätserklärung

Sehr geehrte Damen und Herren,

Wir, Sunoptic International Ltd, erklären in alleiniger Verantwortung, dass die Produkte, auf die sich diese Erklärung bezieht, den folgenden Standards entsprechen:

Name des Herstellers (SRN): **SUNOPTIC INTERNATIONAL Ltd. (GB-MF-000009257)**

Autorisierter Vertreter (SRN): **Sunoptic Europe BVBA (BE-AR-000003314)**

Produktname: **Optische Fassungen TR90 Mix Vollrand (Modelle siehe Anhang)**

Produktbeschreibung: **Optische Rahmen, die den richtigen Abstand zwischen den Linsen und die Ausrichtung relativ zu jedem Auge gewährleisten**

Markenname: **Sunoptic / Montana**

Produktidentifikation durch : **Produktname auf polybeutel**

Risikoklasse: **Klasse I – unsteril, keine Messfunktion - gemäß Regel 1, Kapitel III, Anhang VIII der EU-Verordnung 2017/745**

Konformitätsbewertungsverfahren: **Gemäß Artikel 52 Absatz 7 für Medizinprodukte**

Nomenklatur: **Code (UMDNS) 11-667, GMDN-Code 32816**

Grundlegende UDI-DI : **50558608fra-TR90-mix-frLH**

Alle Produkte sind mit dem CE-Logo gekennzeichnet. Die CE-Kennzeichnung auf den Produkten und/oder ihrer Verpackung bedeutet, dass diese unter Bezugnahme auf die technischen Spezifikationen der europäischen Behörden hergestellt wurden.

Die von uns hergestellten Brillengestelle entsprechen den Spezifikationen und Anforderungen der europäischen Verordnung über Medizinprodukte:

(EU) 2017/745. Konform mit EN ISO 12870

Verordnung (EG) Nr. 1907/2006

Sunoptic International Ltd.

Belgium, 01.01.2022

Bob Kenter
Director



ANNEX:

MODEL+ COLOR	GTIN	MATERIAL	RIM
MTR-90	5055860868562	TR90 - Mix	Fullrim
MTR-90A	5055860868579	TR90 - Mix	Fullrim
MTR-90B	5055860868586	TR90 - Mix	Fullrim
MTR-90C	5055860868593	TR90 - Mix	Fullrim
MTR-90D	5055860868609	TR90 - Mix	Fullrim
MTR-90E	5055860868616	TR90 - Mix	Fullrim
MTR-90F	5055860868623	TR90 - Mix	Fullrim
MTR-90G	5055860868630	TR90 - Mix	Fullrim
MTR-91	5055860868487	TR90 - Mix	Fullrim
MTR-91A	5055860868494	TR90 - Mix	Fullrim
MTR-91B	5055860868500	TR90 - Mix	Fullrim
MTR-91C	5055860868517	TR90 - Mix	Fullrim
MTR-91D	5055860868524	TR90 - Mix	Fullrim
MTR-91E	5055860868531	TR90 - Mix	Fullrim
MTR-91F	5055860868548	TR90 - Mix	Fullrim
MTR-91G	5055860868555	TR90 - Mix	Fullrim
MTR-92	5055860869316	TR90 - Mix	Fullrim
MTR-92A	5055860869323	TR90 - Mix	Fullrim
MTR-92B	5055860869330	TR90 - Mix	Fullrim
MTR-92C	5055860869347	TR90 - Mix	Fullrim
MTR-92D	5055860869354	TR90 - Mix	Fullrim
MTR-92E	5055860869361	TR90 - Mix	Fullrim
MTR-92F	5055860869378	TR90 - Mix	Fullrim
MTR-92G	5055860869385	TR90 - Mix	Fullrim
MTR-93	5055860869392	TR90 - Mix	Fullrim
MTR-93A	5055860869408	TR90 - Mix	Fullrim
MTR-93B	5055860869415	TR90 - Mix	Fullrim
MTR-93C	5055860869422	TR90 - Mix	Fullrim
MTR-93D	5055860869439	TR90 - Mix	Fullrim
MTR-93E	5055860869446	TR90 - Mix	Fullrim
MTR-93F	5055860869453	TR90 - Mix	Fullrim
MTR-93G	5055860869460	TR90 - Mix	Fullrim
MTR-94	5055860866636	TR90 - Mix	Fullrim
MTR-94A	5055860866643	TR90 - Mix	Fullrim
MTR-94B	5055860866650	TR90 - Mix	Fullrim
MTR-94C	5055860866667	TR90 - Mix	Fullrim
MTR-94D	5055860866674	TR90 - Mix	Fullrim

MTR-94E	5055860866681	TR90 - Mix	Fullrim
MTR-94F	5055860866698	TR90 - Mix	Fullrim
MTR-94G	5055860866704	TR90 - Mix	Fullrim
MTR-95	5055860866551	TR90 - Mix	Fullrim
MTR-95A	5055860866568	TR90 - Mix	Fullrim
MTR-95B	5055860866575	TR90 - Mix	Fullrim
MTR-95C	5055860866582	TR90 - Mix	Fullrim
MTR-95D	5055860866599	TR90 - Mix	Fullrim
MTR-95E	5055860866605	TR90 - Mix	Fullrim
MTR-95F	5055860866612	TR90 - Mix	Fullrim
MTR-95G	5055860866629	TR90 - Mix	Fullrim
MTR-96	5055860866476	TR90 - Mix	Fullrim
MTR-96A	5055860866483	TR90 - Mix	Fullrim
MTR-96B	5055860866490	TR90 - Mix	Fullrim
MTR-96C	5055860866506	TR90 - Mix	Fullrim
MTR-96D	5055860866513	TR90 - Mix	Fullrim
MTR-96E	5055860866520	TR90 - Mix	Fullrim
MTR-96F	5055860866537	TR90 - Mix	Fullrim
MTR-96G	5055860866544	TR90 - Mix	Fullrim
MTR-97	5055860866391	TR90 - Mix	Fullrim
MTR-97A	5055860866407	TR90 - Mix	Fullrim
MTR-97B	5055860866614	TR90 - Mix	Fullrim
MTR-97C	5055860866421	TR90 - Mix	Fullrim
MTR-97D	5055860866438	TR90 - Mix	Fullrim
MTR-97E	5055860866445	TR90 - Mix	Fullrim
MTR-97F	5055860866452	TR90 - Mix	Fullrim
MTR-97G	5055860866469	TR90 - Mix	Fullrim
MTR-98	5055860866315	TR90 - Mix	Fullrim
MTR-98A	5055860866322	TR90 - Mix	Fullrim
MTR-98B	5055860866339	TR90 - Mix	Fullrim
MTR-98C	5055860866346	TR90 - Mix	Fullrim
MTR-98D	5055860866353	TR90 - Mix	Fullrim
MTR-98E	5055860866360	TR90 - Mix	Fullrim
MTR-98F	5055860866377	TR90 - Mix	Fullrim
MTR-98G	5055860866384	TR90 - Mix	Fullrim
MTR-99	5055860866230	TR90 - Mix	Fullrim
MTR-99A	5055860866247	TR90 - Mix	Fullrim
MTR-99B	5055860866254	TR90 - Mix	Fullrim
MTR-99C	5055860866261	TR90 - Mix	Fullrim
MTR-99D	5055860866278	TR90 - Mix	Fullrim
MTR-99E	5055860866285	TR90 - Mix	Fullrim
MTR-99F	5055860866292	TR90 - Mix	Fullrim

MTR-99G	5055860866308	TR90 - Mix	Fullrim
M-MTR582	5055860868715	TR90 - Mix	Fullrim
M-MTR582A	5055860868722	TR90 - Mix	Fullrim
M-MTR582B	5055860868739	TR90 - Mix	Fullrim
M-MTR582C	5055860868746	TR90 - Mix	Fullrim
M-MTR582D	5055860868753	TR90 - Mix	Fullrim
M-MTR582E	5055860868760	TR90 - Mix	Fullrim
M-MTR582F	5055860868777	TR90 - Mix	Fullrim
M-MTR583	5055860868647	TR90 - Mix	Fullrim
M-MTR583A	5055860868654	TR90 - Mix	Fullrim
M-MTR583B	5055860868661	TR90 - Mix	Fullrim
M-MTR583C	5055860868678	TR90 - Mix	Fullrim
M-MTR583D	5055860868685	TR90 - Mix	Fullrim
M-MTR583E	5055860868692	TR90 - Mix	Fullrim
M-MTR583F	5055860868708	TR90 - Mix	Fullrim
TR-97	5055860869651	TR90 - Mix	Fullrim
TR-97A	5055860869668	TR90 - Mix	Fullrim
TR-97B	5055860869675	TR90 - Mix	Fullrim
TR-97C	5055860869682	TR90 - Mix	Fullrim
TR-97D	5055860869699	TR90 - Mix	Fullrim
TR-97E	5055860869705	TR90 - Mix	Fullrim
TR-98	5055860869712	TR90 - Mix	Fullrim
TR-98A	5055860869729	TR90 - Mix	Fullrim
TR-98B	5055860869736	TR90 - Mix	Fullrim
TR-98C	5055860869743	TR90 - Mix	Fullrim
TR-98D	5055860869750	TR90 - Mix	Fullrim
TR-98E	5055860869767	TR90 - Mix	Fullrim
TR-99	5055860868050	TR90 - Mix	Fullrim
TR-99A	5055860868067	TR90 - Mix	Fullrim
TR-99B	5055860868074	TR90 - Mix	Fullrim
TR-99C	5055860868081	TR90 - Mix	Fullrim
TR-99D	5055860868098	TR90 - Mix	Fullrim
TR-99E	5055860868104	TR90 - Mix	Fullrim
TR-100	5055860867992	TR90 - Mix	Fullrim
TR-100A	5055860868005	TR90 - Mix	Fullrim
TR-100B	5055860868012	TR90 - Mix	Fullrim
TR-100C	5055860868029	TR90 - Mix	Fullrim
TR-100D	5055860868036	TR90 - Mix	Fullrim
TR-100E	5055860868043	TR90 - Mix	Fullrim
TRC-24	5055860877540	TR90 - Mix	Fullrim
TRC-24A	5055860877557	TR90 - Mix	Fullrim
TRC-24B	5055860877564	TR90 - Mix	Fullrim

TRC-24C	5055860877571	TR90 - Mix	Fullrim
TRC-25	5055860875188	TR90 - Mix	Fullrim
TRC-25A	5055860875195	TR90 - Mix	Fullrim
TRC-25B	5055860875201	TR90 - Mix	Fullrim
TRC-25C	5055860875218	TR90 - Mix	Fullrim
TRC-25D	5055860875225	TR90 - Mix	Fullrim
TRC-25E	5055860876222	TR90 - Mix	Fullrim
TRC-25F	5055860876239	TR90 - Mix	Fullrim
TRC-25G	5055860876246	TR90 - Mix	Fullrim
TRC-26	5055860874983	TR90 - Mix	Fullrim
TRC-26A	5055860874990	TR90 - Mix	Fullrim
TRC-26B	5055860875003	TR90 - Mix	Fullrim
TRC-26C	5055860875010	TR90 - Mix	Fullrim
TRC-26D	5055860875027	TR90 - Mix	Fullrim
TRC-26E	5055860876253	TR90 - Mix	Fullrim
TRC-26F	5055860876260	TR90 - Mix	Fullrim
TRC-26G	5055860876277	TR90 - Mix	Fullrim
TRC-27	5055860872897	TR90 - Mix	Fullrim
TRC-27A	5055860872903	TR90 - Mix	Fullrim
TRC-27B	5055860872910	TR90 - Mix	Fullrim
TRC-27C	5055860872927	TR90 - Mix	Fullrim
TRC-27D	5055860872934	TR90 - Mix	Fullrim
TRC-27E	5055860876284	TR90 - Mix	Fullrim
TRC-27F	5055860876291	TR90 - Mix	Fullrim
TRC-27G	5055860876307	TR90 - Mix	Fullrim
TRC-28	5055860872941	TR90 - Mix	Fullrim
TRC-28A	5055860872958	TR90 - Mix	Fullrim
TRC-28B	5055860872965	TR90 - Mix	Fullrim
TRC-28C	5055860872972	TR90 - Mix	Fullrim
TRC-28D	5055860872989	TR90 - Mix	Fullrim
TRC-28E	5055860876314	TR90 - Mix	Fullrim
TRC-28F	5055860876321	TR90 - Mix	Fullrim
TRC-28G	5055860876338	TR90 - Mix	Fullrim
TRC-29	5055860872996	TR90 - Mix	Fullrim
TRC-29A	5055860873009	TR90 - Mix	Fullrim
TRC-29B	5055860873016	TR90 - Mix	Fullrim
TRC-29C	5055860873023	TR90 - Mix	Fullrim
TRC-29D	5055860873030	TR90 - Mix	Fullrim
TRC-29E	5055860876345	TR90 - Mix	Fullrim
TRC-29F	5055860876352	TR90 - Mix	Fullrim
TRC-29G	5055860876369	TR90 - Mix	Fullrim
TRC-30	5055860873047	TR90 - Mix	Fullrim

TRC-30A	5055860873054	TR90 - Mix	Fullrim
TRC-30B	5055860873061	TR90 - Mix	Fullrim
TRC-30C	5055860873078	TR90 - Mix	Fullrim
TRC-30D	5055860873085	TR90 - Mix	Fullrim
TRC-30E	5055860876376	TR90 - Mix	Fullrim
TRC-30F	5055860876383	TR90 - Mix	Fullrim
TRC-30G	5055860876390	TR90 - Mix	Fullrim
TRC-184	5055860879681	TR90 - Mix	Fullrim
TRC-184A	5055860879698	TR90 - Mix	Fullrim
TRC-184B	5055860879704	TR90 - Mix	Fullrim
TRC-184C	5055860879711	TR90 - Mix	Fullrim
TRC-184D	5055860885736	TR90 - Mix	Fullrim
TRC-185	5055860876581	TR90 - Mix	Fullrim
TRC-185A	5055860876598	TR90 - Mix	Fullrim
TRC-185B	5055860876604	TR90 - Mix	Fullrim
TRC-185C	5055860876611	TR90 - Mix	Fullrim
TRC-185D	5055860885729	TR90 - Mix	Fullrim
TRC-186	5055860876628	TR90 - Mix	Fullrim
TRC-186A	5055860876635	TR90 - Mix	Fullrim
TRC-186B	5055860876642	TR90 - Mix	Fullrim
TRC-186C	5055860876659	TR90 - Mix	Fullrim
TRC-186D	5055860885712	TR90 - Mix	Fullrim
TRC-187	5055860876666	TR90 - Mix	Fullrim
TRC-187A	5055860876673	TR90 - Mix	Fullrim
TRC-187B	5055860876680	TR90 - Mix	Fullrim
TRC-187C	5055860876697	TR90 - Mix	Fullrim
TRC-187D	5055860885705	TR90 - Mix	Fullrim
TRC-188	5055860876703	TR90 - Mix	Fullrim
TRC-188A	5055860876710	TR90 - Mix	Fullrim
TRC-188B	5055860876727	TR90 - Mix	Fullrim
TRC-188C	5055860876734	TR90 - Mix	Fullrim
TRC-189	5055860876741	TR90 - Mix	Fullrim
TRC-189A	5055860876758	TR90 - Mix	Fullrim
TRC-189B	5055860876765	TR90 - Mix	Fullrim
TRC-189C	5055860876772	TR90 - Mix	Fullrim
TRC-190	5055860876789	TR90 - Mix	Fullrim
TRC-190A	5055860876796	TR90 - Mix	Fullrim
TRC-190B	5055860876802	TR90 - Mix	Fullrim
TRC-190C	5055860876819	TR90 - Mix	Fullrim
TRC-191	5055860876826	TR90 - Mix	Fullrim
TRC-191A	5055860876833	TR90 - Mix	Fullrim
TRC-191B	5055860876840	TR90 - Mix	Fullrim

TRC-191C	5055860877489	TR90 - Mix	Fullrim
TRC-191D	5055860885699	TR90 - Mix	Fullrim
TRC-192	5055860876857	TR90 - Mix	Fullrim
TRC-192A	5055860876864	TR90 - Mix	Fullrim
TRC-192B	5055860876871	TR90 - Mix	Fullrim
TRC-192C	5055860877496	TR90 - Mix	Fullrim
TRC-193	5055860876888	TR90 - Mix	Fullrim
TRC-193A	5055860876895	TR90 - Mix	Fullrim
TRC-193B	5055860876901	TR90 - Mix	Fullrim
TRC-193C	5055860877502	TR90 - Mix	Fullrim
TRC-194	5055860876918	TR90 - Mix	Fullrim
TRC-194A	5055860876925	TR90 - Mix	Fullrim
TRC-194B	5055860876932	TR90 - Mix	Fullrim
TRC-194C	5055860876949	TR90 - Mix	Fullrim
TRC-195	5055860876956	TR90 - Mix	Fullrim
TRC-195A	5055860876963	TR90 - Mix	Fullrim
TRC-195B	5055860876970	TR90 - Mix	Fullrim
TRC-195C	5055860876987	TR90 - Mix	Fullrim
TRC-196	5055860876994	TR90 - Mix	Fullrim
TRC-196A	5055860877007	TR90 - Mix	Fullrim
TRC-196B	5055860877014	TR90 - Mix	Fullrim
TRC-196C	5055860877021	TR90 - Mix	Fullrim
M-TRC293	5055860884739	TR90 - Mix	Fullrim
M-TRC293A	5055860884746	TR90 - Mix	Fullrim
M-TRC293B	5055860884753	TR90 - Mix	Fullrim
M-TRC293C	5055860884760	TR90 - Mix	Fullrim
M-TRC294	5055860884814	TR90 - Mix	Fullrim
M-TRC294A	5055860884821	TR90 - Mix	Fullrim
M-TRC294B	5055860884838	TR90 - Mix	Fullrim
M-TRC294C	5055860884845	TR90 - Mix	Fullrim
M-TRC295	5055860884890	TR90 - Mix	Fullrim
M-TRC295A	5055860884906	TR90 - Mix	Fullrim
M-TRC295B	5055860884913	TR90 - Mix	Fullrim
M-TRC295C	5055860884920	TR90 - Mix	Fullrim
M-TRC296	5055860884975	TR90 - Mix	Fullrim
M-TRC296A	5055860884982	TR90 - Mix	Fullrim
M-TRC296B	5055860884999	TR90 - Mix	Fullrim
M-TRC296C	5055860885002	TR90 - Mix	Fullrim
M-TRC297	5055860879605	TR90 - Mix	Fullrim
M-TRC297A	5055860879612	TR90 - Mix	Fullrim
M-TRC297B	5055860879629	TR90 - Mix	Fullrim
M-TRC297C	5055860879636	TR90 - Mix	Fullrim



Sunoptic International Ltd.
79 College Road,
Harrow, Middlesex
HA1 1BD, UK

Authorized representative :
Sunoptic Europe BV
Neerveld 11
2550 Kontich, BE

M-TRC298	5055860879520	TR90 - Mix	Fullrim
M-TRC298A	5055860879537	TR90 - Mix	Fullrim
M-TRC298B	5055860879544	TR90 - Mix	Fullrim
M-TRC298C	5055860879551	TR90 - Mix	Fullrim
M-TRC299	5055860879445	TR90 - Mix	Fullrim
M-TRC299A	5055860879452	TR90 - Mix	Fullrim
M-TRC299B	5055860879469	TR90 - Mix	Fullrim
M-TRC299C	5055860879476	TR90 - Mix	Fullrim
M-TRC300	5055860879360	TR90 - Mix	Fullrim
M-TRC300A	5055860879377	TR90 - Mix	Fullrim
M-TRC300B	5055860879384	TR90 - Mix	Fullrim
M-TRC300C	5055860879391	TR90 - Mix	Fullrim

